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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,126	03/30/2001	Hassan A. Serhan	DEP0546	8872
7590 01/09/2006			EXAMINER	
Philip S. Johnson Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933			MANAHAN, TODD E	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/822,126	SERHAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Todd E. Manahan	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 19-23, 25-28, 30, 36-48, 58-65, 67-79 and 81 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 19-23, 25-28, 40-48, 58-65 and 73-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-12, 30, 36-39, 67-72, 81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Claims 2-4, 19-23, 25-28, 40-48, 58-65, 73-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03 February 2003.

### *Claim Rejections - 35 USC § 102*

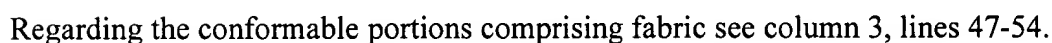
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-12, 67-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Mansat (United States Patent No. 4,728,329).

Mansat discloses a connection system comprising a ligament and first and second bone fasteners. The ligament is made of a braided fabric and includes a central portion, first and second end portions and first and second conformable portions disposed between the end portions and the central portion. The fasteners may be shoulderless. Regarding claim 1, for applicant's convenience, figure 1 has been reproduced below with the claimed element clearly marked:



**bone fastener.**  
Note that it has  
no shoulders and  
thus is  
"shoulderless"

This diagram illustrates a shoulderless bone fastener assembly. A central bone is shown with a longitudinal slot. A bone fastener, labeled 2, is inserted into this slot. The fastener has a textured, cross-hatched surface. A screw, labeled 6, is used to secure the fastener. The screw has a head labeled 1a and a shaft labeled 1b. The screw is inserted through the bone and the fastener. The end of the bone is labeled 7. The text "end portion" is written at the bottom left of the diagram.

**Fig.3**

Note that the shape of the end portions is such that they cooperate to connect with the bone fasteners. The claim requires nothing more. Regarding claim 5, see column 3, lines 55-57 which state that the device can be placed under a tensile loading, i.e. it is “tensionable”. Regarding

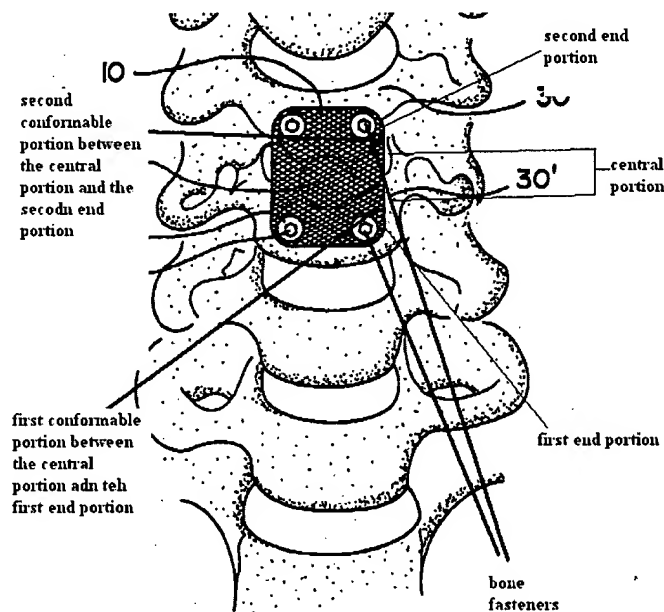
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claim 6, see column 3, lines 35 and 36, which state: "each element is braided..." Regarding claim 7, see column 3, lines 55-57 which state that the device can be placed under a tensile loading, i.e. it is "tensionable". Regarding claim 8, note figure 1. In that the central portion can be demarked anywhere as can the conformable portions, the central portion can be demarcated in such a manner that it has a length twice that of the conformable portions. Regarding claim 9, see column 3, lines 21-29, which state that the device has "longitudinal stretch" and thus is "extensible". Regarding claim 10, see column 3, lines 35 and 36, which state: "each element is braided..." Regarding claim 11, see column 3, lines 21-29, which state that the device has "longitudinal stretch" and thus is "extensible". Regarding claim 12, in that the central portion can be demarcated anywhere as can the conformable portions, the central portion can be demarcated in such a manner that it has a length twice that of the conformable portions. Regarding claim 67, the first and second conformable portions above constitute the first and second intermediate portion. Regarding claim 68, see column 3, lines 43-46 which recite that the device has a longitudinal stretch of 5% to 25%. Regarding claim 69, see column 3, lines 47-55 which state the device is made of yarns, i.e. a textile. Regarding claim 70, see also column 3, lines 47-55 stating the device is made of yarn and also see column 3, lines 35 and 36, which state: "each element is braided..." Regarding claim 71, see column 3, lines 21-29, which state that the device has "longitudinal stretch" and thus is "extensible". Regarding claim 72, in that the central portion can be demarcated anywhere as can the conformable portions, the central portion can be demarcated in such a manner that it has a length twice that of the conformable portions.

Claims 1, 5, 7-9, 11, 12, 30, 36-39, 67-69, 71, 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Yuan et al. (United States Patent No. 5,681,310).

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Yuan et al. disclose an intervertebral connection system comprising a ligament 10 and first and second bone fasteners 20 as clearly seen in figure 1 and as set forth in column 2, line 65 through column 3, line 31. The ligament is made of a fabric such as DACRON, see column 1, lines 61-63, and includes a central portion, first and second end portions and first and second conformable portions disposed between the end portions and the central portion. It is noted that the mat is flexible, see column 1, line 64, and thus all the portions would be “conformable.” Regarding claim 1, for applicant’s convenience, figure 1 has been reproduced below with the claimed element clearly marked:



**FIG. 1**

The end portions have a shape such that they cooperatively connect with the bone fasteners, i.e. via a hole. The fasteners may be shoulderless (see figure 5). Regarding claims 5 and 7, see column 1, line 65 which states that the device may be woven. It is noted that woven DACRON can be placed under tension, i.e. “tensionable”. Regarding claim 6, see column 3, lines 35 and

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36, which state: "each element is braided..." Regarding claim 8, note figure 1. In that the central portion can be demarked anywhere as can the conformable portions, the central portion can be demarcated in such a manner that it has a length twice that of the conformable portions.

Regarding claims 9 and 11, woven DACRON has some stretchability and thus is "extensible".

Regarding claim 12, in that the central portion can be demarcated anywhere as can the conformable portions, the central portion can be demarcated in such a manner that it has a length twice that of the conformable portions. Regarding claim 67, the first and second conformable portions above constitute the first and second intermediate portion. Regarding claim 69, the device is made of DACRON which is a textile.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mansat.

Mansat discloses the claimed invention except for it being made of PLA/PLG copolymer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the device of PLA/PLG copolymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

***Response to Arguments***

Applicant's arguments filed 28 October 2005 have been fully considered but they are not persuasive. It is believed that the above very detailed rejection of the claims in the application is fully responsive to applicant's arguments that the references do not disclose each and every element of the claims.

Applicant's arguments with respect to claim 30 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The new limitation of the device being of PLA/PGA copolymer necessitated the new grounds of rejection.

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



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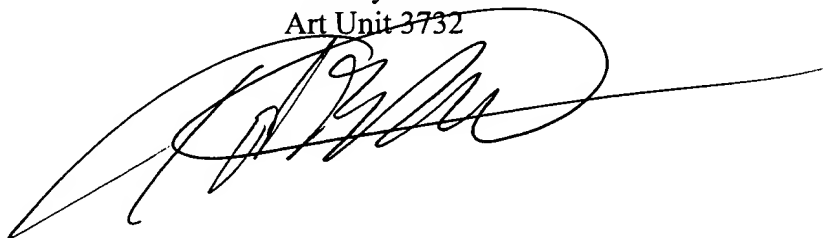
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd E. Manahan whose telephone number is 571 272- 4713. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 571 273-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Todd E. Manahan  
Primary Examiner  
Art Unit 3732

T.E. Manahan  
4 January 2006

A handwritten signature in black ink, appearing to read 'T.E. Manahan', is written over the printed name and title. The signature is stylized with a large loop and a long horizontal stroke extending to the right.